OLSSON, FRANK AND WEEDA, P.C.

ATTORNEYS AT LAW
SUITE 400
1400 SIXTEENTH STREET, N.W.
WASHINGTON, D.C. 20036-2220
(202) 789-1212
FACSIMILE (202) 234-3550

PHILIP C. OLSSON
RICHARD L. FRANK
DAVID F. WEEDA (1948-2001)
DENNIS R. JOHNSON
ARTHUR Y. TSIEN
JOHN W. BODE*
STEPHEN D. TERMAN
MARSHALL L. MATZ
MICHAEL J. O'FLAHERTY
DAVID L. DURKIN
NEIL F. O'FLAHERTY
PAMELA J. FURMAN
BRETT T. SCHWEMER

*PRACTICE WITHIN THE DISTRICT OF COLUMBIA IS LIMITED TO MATTERS AND PROCEDURES BEFORE FEDERAL COURTS AND AGENCIES

TISH E. PAHL
ROBERT A. HAHN
NAOMI J. L. HALPERN
STEPHEN L. LACEY
EVAN P. PHELPS
VALERIE B. SOLOMON

OF COUNSEL
JUR T. STROBOS
JACQUELINE H. EAGLE
KENNETH D. ACKERMAN
MARK L. ITZKOFF

SR. GOVERNMENT AFFAIRS ADVISOR
JOHN R. BLOCK
BRIAN E. JOHNSON
SALLY S. DONNER

Sender's Direct Phone (202) 518-6327
Sender's Direct Facsimile (202) 234-2686

August 13, 2004

BY ELECTRONIC MAIL

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 2004N-0257

Dear Sir/Madam:

On behalf of our client, NOVA Chemicals, Inc., of Pittsburgh, Pennsylvania, we are hereby submitting the following comments regarding the Food and Drug Administration's (FDA) proposed rule to establish recordkeeping requirements for human food and cosmetics manufactured from, processed with, or otherwise containing material from cattle. 69 Fed. Reg. 42275 (July 14, 2004). Specifically, NOVA Chemicals requests that plastic resins made with tallow derivatives be excluded from the proposed recordkeeping and certification requirements.

NOVA Chemicals is a manufacturer of several different plastic packaging resins, including polyethylene and polystyrene. These resins are produced at 14 sites both within the United States and in foreign facilities. Much of the plastic resin produced is used in food packaging, such as plastic bags and plastic containers intended to hold food. In addition, many of these resins use tallow derivatives as processing aids. NOVA Chemicals believes that the proposed rule unintentionally will impose recordkeeping requirements on both the NOVA Chemicals facilities and their customers, while FDA has implicitly acknowledged that such requirements are not needed to protect the public health.

The rule proposed to be promulgated at 21 C.F.R. §189.5(c)(1) would require manufacturers and processors of human food and cosmetic products that are manufactured from, processed with, or otherwise contain material from cattle to maintain records sufficient to demonstrate that no "prohibited cattle materials" were used in manufacturing or processing. The proposed rule would apply to manufacturers and processors of food packaging, because it uses the broad statutory definition of "food" in § 201(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 321(f)).[1] In the case of imported food and cosmetic products that are manufactured from, processed with, or otherwise contain material from cattle, the importer would be required to certify electronically at the time of import entry that it is in compliance with the recordkeeping requirement. FDA intends to modify its electronic import entry system to add a field where importers would be able to indicate that they possess the required records.

Although perhaps unintended, the proposed rule is sweeping in its scope.[2] It would impose new recordkeeping requirements on every manufacturer or processor of food, including food packaging materials, that uses any ingredient or processing aid originally derived from cattle. Because the proposed rule does not define "material from cattle," it apparently applies to any food manufacturer or processor that uses any material derived from cattle, throughout the entire production chain.[3]

In the case of plastic, the proposed rule's recordkeeping requirements (and its electronic certification requirements for importers) would apply to all of the following:

---

[1] "The definitions and interpretations of terms contained in section 201 of the Federal Food, Drug, and Cosmetic Act (the Act) apply to such terms when used in this part." 21 C.F.R. § 189.5(a). 69 Fed. Reg. 42256, 42273 (July 14, 2004). The statutory definition of "food" includes food packaging and other food contact substances that may migrate into food.

[2] The broad scope of the proposed rule is not reflected in FDA's regulatory impact analysis. That analysis estimates that the proposed rule will affect a total of only 575 facilities. 69 Fed. Reg. at 42280. Considering that over 1000 facilities in the United States manufacture plastic resin or plastic food packaging, this must be a gross underestimate. FDA's analysis did not consider the impact of the proposed rule on plastic manufacturing plants.

[3] On July 14, 2004, FDA issued an interim final rule "Use of Materials Derived from Cattle in Human Food and Cosmetics," 69 Fed. Reg. 42256 (July 14, 2004). This rule establishes a new Section of the Food Additive Regulations, Section 189.5 "Prohibited cattle materials." Paragraph (a)(7) of this regulation defines the term "tallow derivative". Since this material is defined in this regulation, it is clear that FDA considers tallow derivatives to be materials derived from cattle.

- A manufacturer of plastic resin that uses tallow derivatives in its manufacturing process, if any of the resin it produces will be used to make food contact articles;

- A downstream manufacturer or processor of plastic food packaging made with such resin; and

- A manufacturer or processor of food products that uses such plastic packaging.

This is true even though the only cattle materials involved are the tallow derivatives used in the manufacture of the plastic resin.[4] Moreover, in the case of plastic resin, plastic food packaging, and foods packaged in plastic that are imported into the United States, the importer would be required to retain the required records and to certify compliance to FDA at the time of import entry.

Imposing these recordkeeping requirements with respect to tallow derivatives in plastic resins is unnecessary when the manufacture of plastic resin uses no cattle materials other than tallow derivatives. Tallow derivatives are not "prohibited cattle materials" under the proposed rule. It seems to NOVA Chemicals that it is an unnecessary burden to require that NOVA Chemicals and its customers retain records for two years showing that each lot of plastic resin produced uses no cattle materials other than tallow derivatives.

We urge FDA to provide an exemption for plastic resin and plastic packaging. This could be accomplished by either revising paragraph § 189.5(a)(7) to read as follows:

> (7) *Tallow derivative* means any chemical obtained through initial hydrolysis, saponification, or trans-esterification of tallow; chemical conversion of material obtained by hydrolysis, saponification, or trans-esterification may be applied to obtain the desired product. Tallow derivatives shall not be considered to be materials derived from cattle for the purposes of paragraph (c) of this section.

Or by adding a new paragraph, § 189.5(c)(8), to read as follows:

---

[4] Under the proposed rule, tallow derivatives are not "prohibited cattle materials." The proposed rule defines "tallow derivative" to mean "any chemical obtained through initial hydrolysis, saponification, or transesterification of tallow; chemical conversion of material obtained by hydrolysis, saponification, or transesterification may be applied to obtain the desired product."

(8) The requirements in paragraphs (c)(1) through (7) do not apply to manufacturers, processors, or importers of plastic resin and/or plastic food packaging containing tallow derivatives.

On behalf of NOVA Chemicals, we appreciate this opportunity to comment on the proposed rule.

Respectfully submitted,

Mark L. Itzkoff

Mark L. Itzkoff
Olsson, Frank and Weeda, P.C.

cc: Office of Information and Regulatory Affairs
Office of Management and Budget
Attn: Fumie Yokota, Desk Officer for FDA